

Title (en)
Novel albumin-free factor VIII formulations

Title (de)
Neue albuminfreie Faktor VIII Formulierungen

Title (fr)
Nouvelles formulations de facteur VIII sans albumine

Publication
EP 1820516 A2 20070822 (EN)

Application
EP 06077229 A 20000222

Priority
• EP 00907322 A 20000222
• US 25527999 A 19990222
• US 45275299 A 19991201

Abstract (en)
A Factor VIII composition formulated without albumin, comprising the following formulation excipients in addition to Factor VIII: 4% to 10% of a bulking agent selected from the group consisting of mannitol, glycine and alanine; 1% to 4% of a stabilizing agent selected from the group consisting of sucrose, trehalose, raffinose, and arginine; 1 mM to 5 mM calcium salt; 100 mM to 300 mM NaCl; and a buffering agent for maintaining a pH of approximately between 6 and 8. Alternatively, the formulation can comprise 2% to 6% hydroxyethyl starch; 1% to 4% of a stabilizing agent selected from the group consisting of sucrose, trehalose, raffinose, and arginine; 1 mM to 5 mM calcium salt; 100 mM to 300 mM NaCl; and a buffering agent for maintaining a pH of approximately between 6 and 8. In a further embodiment, the formulation can comprise: 300 mM to 500 mM NaCl; 1% to 4% of a stabilizing agent selected from the group consisting of sucrose, trehalose, raffinose, and arginine; 1 mM to 5 mM calcium salt; and a buffering agent.

IPC 8 full level
A61K 38/37 (2006.01); **A61K 47/10** (2006.01); **A61K 9/19** (2006.01); **A61K 38/43** (2006.01); **A61K 47/02** (2006.01); **A61K 47/18** (2006.01); **A61K 47/20** (2006.01); **A61K 47/22** (2006.01); **A61K 47/26** (2006.01); **A61K 47/38** (2006.01); **A61K 47/42** (2006.01); **A61P 7/04** (2006.01)

CPC (source: CZ EP US)
A61K 9/0019 (2013.01 - EP US); **A61K 9/19** (2013.01 - CZ EP US); **A61K 38/37** (2013.01 - CZ EP US); **A61K 47/02** (2013.01 - CZ EP US); **A61K 47/10** (2013.01 - EP US); **A61K 47/18** (2013.01 - US); **A61K 47/183** (2013.01 - CZ EP US); **A61K 47/26** (2013.01 - CZ US); **A61K 47/38** (2013.01 - EP US); **A61P 7/04** (2018.01 - EP); **Y10S 530/829** (2013.01 - EP US)

Citation (applicant)
• WO 9622107 A1 19960725 - QUADRANT HOLDINGS CAMBRIDGE [GB], et al
• US 5328694 A 19940712 - SCHWINN HORST [DE]
• EP 0511234 A1 19921104 - OCTAPHARMA AG [CH], et al

Designated contracting state (EPC)
AT BE CH CY DE DK ES FI FR GB GR IE IT LI LU MC NL PT SE

DOCDB simple family (publication)
WO 0048635 A1 20000824; AT E365052 T1 20070715; AU 2884300 A 20000904; AU 777972 B2 20041104; BR 0008405 A 20020430; BR 0008405 B1 20140422; CA 2362927 A1 20000824; CA 2362927 C 20110712; CA 2634663 A1 20000824; CA 2634663 C 20090825; CA 2634664 A1 20000824; CA 2634664 C 20110809; CA 2634674 A1 20000824; CN 100553678 C 20091028; CN 101683522 A 20100331; CN 101683522 B 20130501; CN 101810854 A 20100825; CN 1399560 A 20030226; CY 1108030 T1 20130904; CY 1113969 T1 20160727; CZ 20012996 A3 20020313; CZ 300547 B6 20090610; CZ 307322 B6 20180606; CZ 307715 A3 20020313; CZ 307715 B6 20190306; DE 60035260 D1 20070802; DE 60035260 T2 20071018; DK 1154796 T3 20070924; DK 1820516 T3 20131028; DK 2130554 T3 20121203; DK 2193809 T3 20150526; EP 1154796 A1 20011121; EP 1154796 B1 20070620; EP 1820516 A2 20070822; EP 1820516 A3 20091007; EP 1820516 B1 20130724; EP 2130554 A1 20091209; EP 2130554 B1 20120905; EP 2193809 A1 20100609; EP 2193809 B1 20150408; EP 2921180 A1 20150923; EP 2921180 B1 20190814; ES 2288843 T3 20080201; ES 2394755 T3 20130205; ES 2435141 T3 20131218; ES 2541470 T3 20150720; HK 1106705 A1 20080320; HK 1133583 A1 20100401; HK 1139862 A1 20100930; HK 1213801 A1 20160715; JP 2003520764 A 20030708; JP 2008201801 A 20080904; JP 2009046499 A 20090305; JP 2012072198 A 20120412; JP 2014024864 A 20140206; JP 2015091902 A 20150514; JP 2016040310 A 20160324; JP 2017125076 A 20170720; JP 2018172413 A 20181108; JP 5006832 B2 20120822; JP 5140539 B2 20130206; JP 5149470 B2 20130220; JP 5596064 B2 20140924; JP 6038003 B2 20161207; JP 6155442 B2 20170705; JP 6253627 B2 20171227; MX PA01008515 A 20030606; PL 198123 B1 20080530; PL 203177 B1 20090930; PL 203893 B1 20091130; PL 204701 B1 20100226; PL 356453 A1 20040628; PT 1154796 E 20070928; PT 1820516 E 20131031; PT 2130554 E 20121119; PT 2193809 E 20150824; RU 2244556 C2 20050120; US 2004116345 A1 20040617; US 2006205661 A1 20060914; US 2008176791 A1 20080724; US 2012083446 A1 20120405; US 2013184216 A1 20130718; US 2015025010 A1 20150122; US 2017000854 A1 20170105; US 6586573 B1 20030701; US 7087723 B2 20060808; US 7247707 B2 20070724; US 8058226 B2 20111115; US 8372800 B2 20130212; US 8765665 B2 20140701; US 9352027 B2 20160531; US 9669076 B2 20170606

DOCDB simple family (application)
US 0040068 W 20000222; AT 00907322 T 20000222; AU 2884300 A 20000222; BR 0008405 A 20000222; CA 2362927 A 20000222; CA 2634663 A 20000222; CA 2634664 A 20000222; CA 2634674 A 20000222; CN 00806304 A 20000222; CN 200910171121 A 20000222; CN 200910171124 A 20000222; CY 071101050 T 20070807; CY 121101185 T 20121204; CZ 20012996 A 20000222; CZ 2008827 A 20000222; CZ 2008828 A 20000222; DE 60035260 T 20000222; DK 00907322 T 20000222; DK 06077229 T 20000222; DK 09075396 T 20000222; DK 10075019 T 20000222; EP 00907322 A 20000222; EP 06077229 A 20000222; EP 09075396 A 20000222; EP 10075019 A 20000222; EP 15154020 A 20000222; ES 00907322 T 20000222; ES 06077229 T 20000222; ES 09075396 T 20000222; ES 10075019 T 20000222; HK 07113386 A 20071207; HK 10100752 A 20071207; HK 10106491 A 20071207; HK 16101857 A 20160218; JP 2000599425 A 20000222; JP 2008120035 A 20080501; JP 2008255510 A 20080930; JP 2012009767 A 20120120; JP 2013227977 A 20131101; JP 2015031316 A 20150220; JP 2015220875 A 20151111; JP 2017088289 A 20170427; JP 2018125917 A 20180702; MX PA01008515 A 20000222; PL 35645300 A 20000222; PL 38228800 A 20000222; PL 38229900 A 20000222; PL 38230000 A 20000222; PT 00907322 T 20000222; PT 06077229 T 20000222; PT 09075396 T 20000222; PT 10075019 T 20000222; RU 2001125929 A 20000222; US 201113250789 A 20110930; US 201313760900 A 20130206; US 201414286391 A 20140523; US 201615146835 A 20160504; US 43463406 A 20060515; US 507011100 A 20000222; US 61072303 A 20030701; US 76477007 A 20070618